REMARKS

Applicants submit this Amendment in response to the Office Action mailed on July 17, 2007 and in response to the Notice of Non-Compliant Amendment mailed on January 9, 2008 in relation to the Amendment filed on October 3, 2007. With that Amendment, Applicants submitted a Request for Continued Examination of the application and the applicable fees.

The application has been amended as follows. The specification has been amended in several places to correct typographical errors made in the Amendment filed on May 30, 2007.

The claims have been amended as follows. Claims 1 and 2 have been amended for clarification purposes in response to statements of the Examiner during the interview of August 14, 2007. These amendments clarify that it is the amino acid sequence of the polypeptide that comprises the amino acid sequence of SEQ ID NO: 4. The scope of the claims is not changed by these amendments. Claims 1 and 2 have further been amended to call for a purified polypeptide. Support for this amendment is found in the specification in Example 6 on pages 25 and 26. New claim 48 has been added. Claim 48 is parallel to claim 1, except that the connector "consisting of" is used in claim 48.

I. Rejection of the Claims under 35 U.S.C. §102(b)

A. Rejection of Claims 1 and 2 under 35 U.S.C. §102(b) as anticipated by Park

The Examiner has maintained the rejection of claims 1 and 2 under 35 U.S.C. §102(b) as being anticipated by the disclosure of Park, in Proceedings of the 40th Annual

Meeting of National Mastitis Council, National Council Incorporated, pages 247-248, February 2001. Applicants traverse the rejection of these claims on this ground.

In a Declaration submitted with the Amendment filed on May 30, 2007, Applicant Stephen P. Oliver, one of the authors of the cited Park reference, testified that the methods described in the Park reference do not result in purification of lactoferrin binding protein (LBP, referred to in the present application as SUAM), but rather result in an extraction of LBP from a bacterium along with other bacterial surface proteins and in a visible detection that the protein was indeed contained within the extracted pool of bacterial surface proteins.

Thus, it is submitted that the Park reference does not disclose or suggest a purified polypeptide, as called for in claims 1 and 2.

During the interview of August 14, 2007, the Examiner stated that Park discloses a partial purification because, as stated by the Examiner, the SDS-PAGE procedure of Park is a partial purification. Moreover, the Examiner stated that claims 1 and 2 do not specify a degree of purification of the polypeptide.

It is respectfully submitted that the Examiner is in error. Park discloses that SDS-PAGE was performed on the bacterial surface proteins and that 110 kDa and 112 kDa protein bands were extracted from this protein mixture. As testified by Stephen Oliver in his Declaration, the extracted LBP protein was within the region of the SDS-PAGE gel (110 to 112 kDa) that included this protein along with other bacterial surface proteins of comparable size. Thus, the Park reference does not disclose any purification of LBP, but merely discloses an extraction of LBP from a bacterium along with other surface proteins and a detection that the

extracted LBP resided, along with other extracted proteins of similar size, on a particular segment of the SDS-PAGE gel.

It is for this reason that the Park reference concludes by stating that the SDS extraction method appears to be a suitable method to extract LBP for (subsequent) purification and characterization.

The fact that the Park reference refers solely to extraction and not to purification is evidenced by the present specification and Stephen Oliver in his Declaration testifies that this is so. Example 4, on pages 23-24 of the specification, is a recitation of the disclosure of the Park reference. Example 6, on pages 25-26 of the specification, discloses the purification of the extracted bacterial surface proteins. As disclosed in Example 6, starting with 30 mg of the extracted bacterial surface proteins in 30 ml of PBS (1 mg/ml), 20 micrograms per ml of purified SUAM were obtained. Thus, of the 30 mg of initial protein, a total of 200 micrograms of SUAM (20 micrograms per ml in a total of 10 ml) were obtained.

Thus, of the extracted bacterial surface proteins obtained by the method disclosed in Park, only about 0.66% was SUAM.

In view of the above, Applicants submit that the Park reference does not disclose a purified polypeptide as called for in claims 1 and 2 and the Examiner is respectfully requested to reconsider and to withdraw the rejection of claims 1 and 2 on this ground.

B. Claim 2 - "Consisting Essentially Of"

In the Office Action of July 17, 2007, and during the interview of August 14, 2007, the Examiner stated that the term "consisting essentially of" in claim 2 is construed to have

the same meaning as "comprising." The Examiner stated that the term "consisting essentially of" is construed in this manner when there is an absence of a clear indication in the specification or the claims of what the basic and novel characteristics of the claimed subject matter actually are. For support for this contention, the Examiner cited *PPG Industries v. Guardian Industries Corp.*, 156 F. 3d 1351, 1355, 48 U.S.P.Q.2d 1351, 1355 (Fed. Cir. 1998).

Applicants submit, however, that the cited case is not pertinent to the present application because, in the present application, there is a clear indication of what the basic and novel characteristics of the claimed subject matter are.

In *PPG Industries*, the court stated that, by using the term "consisting essentially of," an Applicant signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. The court further stated that PPG could have defined the scope of the phrase "consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention and that the essential question is whether PPG did so.

PPG attempted to show that their specification did indeed make clear what it regarded as constituting a material change in the basic and novel characteristics of the invention. In doing so, PPG cited the disclosure in their specification that the presence of SO_3 may vary in their production process and would have no significant effect. However, the court stated that this argument means that *ANY EFFECT* of SO_3 is not significant no matter how serious the effect is and, therefore, that there really is no difference between consisting essentially of and consisting in this situation. As noted by the court, the disclosure of PPG regarding SO_3 did not pertain to

the change that SO_3 might cause to the claimed invention, but rather pertained to any change that SO_3 might cause. Because the change on the invention itself that was due to SO_3 was not clarified in the specification, the court was unable to determine if the changes due to SO_3 were of a nature so as to constitute a material change in the basic and novel characteristics of the invention. Thus, there was no guidance in *PPG Industries* as to how to construe the term "consisting essentially of." Therefore, the court held that, in this situation, "consisting essentially of" was the same as "comprising."

The present situation differs markedly from the situation in *PPG Industries*. In the present situation, the specification discloses that the claimed polypeptide elicits an antibody that specifically binds thereto and that this antibody inhibits adherence of *Streptococcus uberis* to, and internalization of *S. uberis* into, bovine mammary epithelial cells.

In contrast to *PPG Industries*, the present specification does provide guidance as to what changes would constitute a material change in the basic and novel characteristics of the invention. It is clear from the specification that a change would be material if such change caused the claimed polypeptide to be incapable of eliciting an antibody that inhibits adherence of *Streptococcus uberis* to, and internalization of *S. uberis* into, bovine mammary epithelial cells.

Because there is a clear indication in the specification of what the basic and novel characteristics of the claimed invention are, Applicants submit that it is improper for the Examiner to construe the term "consisting essentially of" of claim 2 to be equivalent to the term "comprising" in claim 1.

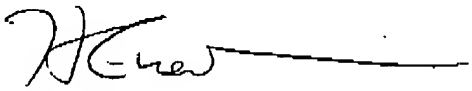
II. New Claim 48

During the interview of August 14, 2007, the Examiner stated that a claim calling for the subject matter of claim 1, as amended herein, and utilizing the connector "consisting of", would be allowable. Applicants herein submit this claim as claim 48 and request the Examiner to find this claim to be allowable.

CONCLUSION

With the Amendment filed on October 3, 2007, Applicants submitted a Request for Continued Examination and the required fees. Applicants submit that the claims, as amended herein, are in condition for allowance and request an early notice to that effect.

Respectfully submitted,



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Attachment in Amendment of 10/3/2007: Request for Continued Examination and required fees

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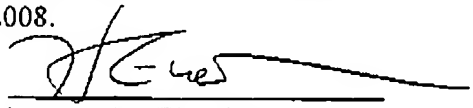
Dated: January 15, 2008



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